DE 3-431-727

DE 3,431,727 A1

Translated from German by the Ralph McElroy Co., Custom Division
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Code: 282-38688

FEDERAL REPUBLIC OF GERMANY

GERMAN PATENT OFFICE

PATENT NO. DE 3,431,727 A1

(Offenlegungsschrift)

Int. Cl.[4]: A 61 K 31/315
A 61 K 9/12

Application No.: P 3,431,727.9

Filing Date: August 29, 1984

Date Laid Open to Public Inspection: March 13, 1986

NASAL SPRAY AGAINST COLDS AND INFLUENZA CONTAINING ZINC GLUCONATE

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Abstract

The invention pertains to a nasal spray for treating viral respiratory illnesses, especially colds and influenza, characterized by containing zinc gluconate.

Claims

1. Pharmaceutical for treating viral illnesses of the respiratory tract, especially colds and influenza, characterized by the fact that it contains zinc gluconate in aqueous solution with stabilizers, preservatives, and other usual pharmaceutical adjuncts.

2. Pharmaceutical according to Claim 1 in the form of a spray.

The present invention pertains to a new nasal spray, which contains zinc gluconate, and its use in the treatment of viral respiratory illnesses, especially colds and influenza.

It is known that a specific remedy against colds, influenza, and other viral illnesses, or against their pathogens, has not heretofore existed.

Symptomatically applied remedies include:

1) Nasal drops and sprays with vasoconstrictive active ingredients, which reduce the swelling of mucous membranes but also cause a reactive, more severe swelling of the mucous membranes of the nose. With longer use of vasoconstrictives, irreversible damage to the nasal membranes has been described.

2) Orally administered preparations, which contain vasoconstrictive substances together with antihistamines and analgesics.

Preparations from both pharmaceutical groups help only to make the cold or the illness more bearable but have no influence on the duration of the illness. Furthermore, the side effects of these preparations must be taken into account.

It is further known that zinc compounds, especially when present in ionizable, dissociable form, exercise an antiviral effect.

The use of zinc sulfate in pharmaceutical preparations for the localized treatment of herpes virus infections has been often described:

J. Shlomai et al., Virology 66:330 (1975),

P. Gupta et al., Proc. Soc. Exp. Biol. Med. 152:455 (1976),

P. O. Tennican et al., Life Science 24:1877 (1979),

P. O. Tennican et al., Proc. Soc. Exp. Biol. Med. 164:593 (1980),

European Patent Application Nos. 0,000,133; 0,012,115; 0,045,282,

German Patent (Offenlegungsschrift) No. 2,715,711.

Until now, zinc sulfate could be applied only locally and also only when its irritating effect on skin and mucous membrane was ameliorated by a special pharmaceutical preparation.

It is known from cell culture experiments that zinc ions inhibit the reproduction of rhinoviruses:

B. E. Butterworth et al., Archives of Virology 51:169 (1976)

B. D. Korant et al., J. Virology 18:298 (1976)

B. D. Korant et al., Nature 248:588 (1974).

The zinc ions inhibit the maturation of the rhinoviruses in that they enter into a reversible reaction with the essential polypeptides.

The irritating effect of the zinc ions on skin and mucous membranes has, however, heretofore precluded a therapeutic application for viral illnesses of the respiratory tract.

G. A. Eby et al. (Antimicrob. Agents Chemother. 25:20 (1984)) were the first to employ zinc gluconate against colds. Here patients with colds were administered 180 mg of zinc gluconate in the form of lozenges every 2 h with positive results. Evaluation of these findings has revealed, however, that the taste of these lozenges is so unpleasantly metallic that, even with strong aromatization or the addition of an anesthetic, no therapeutically useful pharmaceutical can be produced. furthermore, the great quantities of zinc, which the organism must assimilate after swallowing the saliva, cause nausea and regurgitation in many instances. Consequently, a mouthwash and gargling solution was tested, which, due to the unmasked metallic taste, is nonetheless emetic.

The objective of the invention was the development of a pharmaceutical preparation without the known disadvantages and side effects of other preparations of the aforementioned indicational direction. The new preparation should contain the virus-inactivating zinc ions and liberate them in a therapeutically effective yet still nonirritating concentration, to the extent possible at the site of the infection--the nose and throat area.

It has now been surprisingly learned that a diluted zinc gluconate solution in the form of a nasal spray hinders the development of a cold when applied early. Here it is highly important that the zinc gluconate solution be used in an atomizer

(0.14 mL per stroke) in order to achieve maximally uniform distribution onto the mucous membrane in the nose and throat.

The pharmaceutical of the invention for treating viral respiratory illnesses, especially colds and influenza, consists, therefore, of a diluted, aqueous solution of zinc gluconate, which may optionally contain preservatives, stabilizers, and other usual pharmaceutical adjuncts. The concentration of the active ingredient of the pharmaceutical is generally 0.1-5%, preferably 2%.

The finished pharmaceutical preparation is filled into suitable spray bottles and then dispensed in accordance with regulations.

The pharmaceutical preparation of the invention is preferably applied every 1-2 h following the first indications of a cold. Experiments with humans have shown that, with the new preparation and this method of application, a cold did not even break out. There was no irritating effect. The only side effect experienced was an occasional, slight burning sensation, which was not uncomfortable, however. By virtue of its mild astringent effect, the spray restores unimpeded nasal breathing. If a cold has already developed because the pharmaceutical was not applied in time, the progress of the illness is favorably influenced by use of the remedy in accordance with the directions, and the cure is accelerated.

The following example describes the preparation of a nasal spray; it does not, however, restrict the scope of the invention in any way.

Zinc gluconate nasal spray, 2.0%

1 mL contains:

Zinc gluconate	20 mg
Edetic acid disodium salt, $2H_2O$	1 mg
Benzalconium chloride	0.1 mg
Water	978.9 mg

The preparation is filled into suitable spray bottles.